RECEIVED

1761,

JUN 2 5 2003

TECH CENTER 1606/290% F7589(V)

**PATENT** 

UNUS #01-0366-UNI Docket #F7589(V)

PECEIVED
JUN 19 2003
TC 1700

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited...

with the United States Postal Service as First Class Mail in an elope addressed to: Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450°

GERARD J. MCGOWAN, JR.

Reg. No. 29,412 Attorney for Applicant(s) Date of Signature

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

000201

Applicant:

**Customer No:** 

Bodor et al.

Serial No.:

10/072,580

Filed:

February 8, 2002

For:

FOOD PRODUCT SUITABLE FOR REDUCING LOW DENSITY LIPOPROTEIN

**CHOLESTEROL LEVELS** 

Group:

1761

Edgewater, New Jersey 07020

October 8, 2002

## INFORMATION DISCLOSURE STATEMENT

**Commissioner for Patents** P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Documents relating to the above-identified application are submitted herewith. These documents are intended for the Examiner's information and for citation with the instant case. This submission does not constitute either a representation that a thorough search has been made or an admission that the documents cited herein are properly citable against the abovecaptioned patent application. An attached PTO Form 1449 lists all the documents.

06/18/2003 HAHHED1 00000070 121155 10072580

01 FC:1806

180.00 DA

European Search Report (EP 01 20 0493)

International Search Report (PCT/EP 02/00998)

EP 0 556 699 A1

GB 2 046 737 A

WO 99/23996

WO 00/30665

WO 00/64276

United States Food And Drug Administration (FDA), Docket No. 97-0441, Final Decision

United States Food And Drug Administration (FDA) titled: "Reference Amounts Customarily Consumed Per Eating Occasion"

"Types Of Soy Protein Production"; D. H. Waggle and C. W. Kolar; <u>Soy Protein and Human</u>
<a href="Mutrition">Nutrition</a>

"Reduction Of The Cholesterol Content Of Eggs By The Oral Administration Of Lovastatin To Laying Hens"; R. Elkin and J. Rogler; <u>Journal of Agriculture and Food Chemistry</u>; 38 (1990), August, No. 8, Washington D.C.

"Meta-Analysis Of The Effects Of Soy Protein Intake On Serum Lipids"; J. Anderson et al.; The New England Journal Of Medicine; August 3, 1995, pp. 276-282

"Monascus Purpureus-Fermentated Rice (Red Yeast Rice): A Natural Food Product That Lowers Blood Cholesterol In Animal Models Of Hypercholesterolemia"; Li et al.; <u>Nutrition</u> Research; Vol. 18, No. 1, pp. 71-81, 1998

"Cholesterol-Lowering Effects Of A Proprietary Chinese Red-Yeast-Rice Dietary Supplement"; Heber et al.; American Journal of Clinical Nutrition; 1999; 69; pp. 231-236

XP-002203259: "Evaluation Of Genistin and Genistein Contents In Soybean Varieties And Soy Protein Concentrate Prepared With 3 Basic Methods" - abstract

XP-002203260: "Preventive Effect Of Dietary Fermented Soybean On Bone Loss In Ovariectomized Rats: Enhancement With Isoflavone And Zinc Supplementation" - abstract

Under Applicants' Duty of Disclosure, the Examiner is informed of related co-pending applications as follows:

Applicant:

Van Heetvelde et al.

Serial No.:

10/174,146

Filed:

June 18, 2002

FOR:

Oily Paste Which Contains Herbs

Since neither a Final Office Action nor a Notice of Allowance has issued in this application, please consider the enclosed information and charge the \$180.00 fee under 37 C.F.R. § 1.17(p) to Deposit Account No. 12-1155. Please charge any fees or credit overpayment to Deposit Account No. 12-1155. Triplicate copies of this letter are enclosed. (37 CFR 1.97(c)(2))

Respectfully submitted,

Gerard J. McGowan, Jr.

Registration No. 29,412 Attorney for Applicant(s)

GJM/pod (201) 840-2297

## FORM PTO-1449

## INFORMATION DISCLOS STATEMENT BY APPLICAN

ATTORNEY DOCKET NO.:

F7589(V)

SERIAL NO.:

10/072,580

APPLICANT:

Bodor et al.

FILING DATE:

February 8, 2002

RECEIVED TO 19 2003 1614 GROUP: **U.S. PATENT DOCUMENTS** CLASS SUBCLASS DATE DOCUMENT NO. NAME OF INVENTOR FILING DATE **EXAMINER** IF APPROPRIATE **INITIALS** FOREIGN PATENT DOCUMENTS CLASS **EXAMINER** DOCUMENT NO. **PUBLICATION** COUNTRY **SUBCLASS** TRANSLATION YES OR NO **INITIALS** DATE 0 556 699 8/93 Europe 2 046 737 11/80 Great Britain 99/23996 5/99 WO 00/30665 6/00 WO 00/64276 11/00 WO OTHER DOCUMENTS European Search Report (EP 01 20 0493 - dated July 5, 2001) International Search Report (PCT/EP 02/00998) United States Food And Drug Administration (FDA), Docket No. 97-0441, Final Decision United States Food And Drug Administration (FDA) titled: "Reference Amounts Customarily Consumed Per Eating Occasion" "Reduction Of The Cholesterol Content Of Eggs By The Oral Administration Of Lovastatin To Laying Hens"; R. Elkin and J. Rogler; Journal of Agriculture and Food Chemistry; 38 (1990), August, No. 8, Washington D.C. "Meta-Analysis Of The Effects Of Soy Protein Intake On Serum Lipids"; J. Anderson et al.; The New England Journal Of Medicine; August 3, 1995, pp. 276-282

Animal Models Of Hypercholesterolemia"; Li et al.; Nutrition Research; Vol. 18, No. 1, pp. 71-81, 1998 "Cholesterol-Lowering Effects Of A Proprietary Chinese Red-Yeast-Rice Dietary Supplement"; Heber et al.; American Journal of Clinical Nutrition; 1999; 69; pp. 231-236 XP-002203259: "Evaluation Of Genistin and Genistein Contents In Soybean Varieties And Soy Protein Concentrate Prepared With 3 Basic Methods" - abstract XP-002203260: "Preventive Effect Of Dietary Fermented Soybean On Bone Loss In Ovariectomized Rats: Enhancement With Isoflavone And Zinc Supplementation" - abstract Co-pending application for Van Heetvelde et al., Serial No. 10/174,146; Filed June 18, 2003; Case No. F7608(V) DATE CONSIDERED **EXAMINER** 

"Monascus Purpureus-Fermentated Rice (Red Yeast Rice): A Natural Food Product That Lowers Blood Cholesterol In

EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.